IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

DAVID S. ZINK et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	No. 2:12-CV-4209-NKL
	)	
GEORGE A. LOMBARDI et al.,	)	
	)	
Defendants.	)	

AFFIDAVIT OF LARRY D. SASICH

1. My name is Larry D. Sasich, PharmD, MPH, FASHP. I am over the age of twenty-one and competent to testify to the truth of the matters contained herein. The factual statements I make in this affidavit are true and correct to the best of my knowledge and experience. The opinions I express in this statement are made to a reasonable degree of scientific certainty.

2. I am a Consultant specializing in drug safety and efficacy issues. My experience and qualifications, in part, include:

a. Consultant to the Saudi Food and Drug Authority, Riyadh, Saudi Arabia.

b. Chairperson of the Department of Pharmacy Practice at the LECOM School of Pharmacy in Erie, Pennsylvania.

c. Consultant to Public Citizen Health Research Group, Washington, D.C., and

d. Consumer Representative on the Science Board of Food and Drug Administration's Science, an advisory committee to the FDA Commissioner.

3. I have a Masters in Public Health, with an emphasis in biostatistics and epidemiology from the George Washington University, and a Doctorate of Pharmacy from University of the Pacific. I have completed a residency in nuclear pharmacy at the University of New Mexico. I have also been elected a Fellow in the American Society of Health-System Pharmacists (FASHP). I have also authored publications and/or presented analysis on drug safety issues. A complete list of my publications and presentations are listed in my Curriculum Vitae, which is appended to this statement.

4. Counsel representing David Zink et al., a group of Missouri death-sentenced prisoners, have asked me to provide opinions on the use and practice of compounding pharmacy in the United States. In particular, I have been asked to comment on the intention of the Missouri Department of Corrections to employ a compounding pharmacist to compound drugs – in this case pentobarbital - intended for use in lethal injection. Counsel for the prisoners have asked me to

review the processes involved in compounding and assess whether there is a substantial risk of serious harm in using compounded drugs for this purpose.

I. Pharmacy Compounding Review

5. Pharmacy compounding is a traditional practice of the profession of pharmacy. Traditional compounding does not involve the creation of drugs from scratch. It uses active and inactive ingredients to meet the individual needs of a patient that cannot be met with an FDA-approved product for medical reasons, according to a legal prescription for an individual patient. For instance, a two-year-old transplant patient may require a medication that is only available in an FDA-approved tablet form. In such a case, a tablet's ingredients may be reformulated into an oral liquid for administration. This medication would be considered to be life-sustaining, and the expected benefits would likely be judged by the patient's learned intermediary (a licensed healthcare professional who holds prescriptive authority) to outweigh risks associated with the use of a non-FDA approved, non-GMP (Good Manufacturing Practices) produced product. With traditional pharmacy compounding, then, the FDA generally exercises enforcement discretion, as opposed to the non-traditional practice, which is regulated if at all only by the states. Such benefit-risk regulatory decisions are only very rarely made on a population level: during the 2009 Influenza

Pandemic, the FDA made explicit provisions for the compounding of a pediatric version of an antiviral medication that did not exist in a dose or dosage form suitable for children according to a validated compounding formula.

6. The FDA may use its resources to enforce provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA) with respect to compounding in order to ensure that the following restrictions apply:

a. the existence of individual medical necessity that cannot be met with FDA-approved products as determined by a licensed prescriber acting as the learned intermediary, and

b. a tacit understanding that FDA-approval, federal Good Manufacturing Practice, and federal inspection and oversight constitute a basic standard of care for pharmaceuticals in the United States, with a tolerance for circumvention of those standards only under the rarest circumstances of medical necessity.

7. Over the past several decades, marketing experts have leveraged the traditional, medically-driven, therapeutically essential role of compounding—where federal standards are compromised for critical medical need—to legitimize a substandard drug industry, supported and driven by chemical distributors and other entities, who provide training and supply active and inactive ingredients,

compounding equipment, recipes, and marketing tools for growing compounding businesses. This industry operates in a "grey market," where non-federally regulated drug manufacturing, marketing, and promotion throughout the United States is strategically legitimized through consistent messaging around the historical role of drug compounding.

8. Non-traditional compounding pharmacy practice resembles drug manufacturing more than it does the practice of pharmacy. Non-traditional compounding involves the use of raw ingredients to manufacture a copy or substitute for an FDA-approved drug, not for a specific patient with a specific medical need, but for general distribution. In contrast to drug manufacturers, non-traditional compounding pharmacies avoid the costs of drug development and testing to prove their products are pure, potent, safe, and effective. They also avoid the substantial costs associated with maintaining compliance with federal manufacturing oversight. At the same time, they charge equivalent or even higher prices for their products, often using the term "customized" to suggest a designer-quality and impart a perceived added value to the product.

9. Unlike manufacturers, compounding pharmacies are generally not subject to the drug approval process and rigorous checks and regulatory procedures required under federal GMPs. It is questionable whether

compounding pharmacists would even be able to define risks associated with compounding untested and unapproved new drugs when they lack the expertise that federal manufacturing oversight provides.

10. Serious complications are foreseeable when a drug is not manufactured by an approved manufacturer. For example, a compounding pharmacist may mistakenly conclude that drugs made according to the enforceable sterile compounding standards issued by the United States Pharmacopeia (USP) Chapter 797 have a high degree of sterility assurance, compared to the federal standard for sterility. In fact, experts have concluded the opposite: that drugs compounded in accordance with USP Chapter 797 have a low standard of sterility assurance compared to the federal standard. A product's sterility is very basic risk information, yet compounding pharmacies do not generally assess it, much less convey it to prescribers or patients.

11. Similarly, a pharmacist may have confidence in her ability to accurately measure or weigh individual ingredients and extend this confidence as a quality measure for the finished compound. But if the pharmacist is starting with an adulterated or counterfeit chemical that would go unrecognized in a pharmacy setting (as opposed to a manufacturing facility with the capacity to test the quality of ingredients and overseen by federal regulators), accurate

measurement of chemicals cannot remedy an already adulterated or otherwise unsafe product with respect to identity, purity, potency, or harmful contamination. Despite a pharmacist's best efforts, there are parameters beyond her professional control that build risk and uncertainty into all compounded products.

12. Compounded drugs do not meet federal requirements for purity, potency, efficacy and safety. Existing outside of the FDA regulatory framework which ensures the quality, safety and efficacy of manufactured pharmaceutical drugs, compounding pharmacies represent an emerging, substandard drug industry responsible for making large quantities of unregulated, unpredictable and potentially unsafe drugs.

13. Former FDA Commissioner David Kessler, M.D., warned that exempting pharmacy compounding from the FFDC would create a shadow industry of unapproved drug manufacturing, which would create a risk to the public through the manufacture of ineffective or unsafe products. Pharmacists are drug experts, not manufacturing experts. Pharmacists who compound drugs may not understand the complex system of drug regulations that provide necessary public health protections.

14. Compounded drugs are not FDA-approved for any purpose. This means that the FDA has not verified their safety or effectiveness or the quality of their manufacture. Counterfeit or substandard ingredients, and/or poor practice on the part of drug compounders, often results in drugs which are contaminated, sub-potent or super-potent, or which do not have the strength, quality or purity represented on their labeling or required for the safe and effective treatment of patients. The potential harm associated with the use of such contaminated or sub-potent drugs is extremely high. Consumers who use compounded drugs do so at their own risk.

15. Missouri has announced that it will obtain the pentobarbital specified as the lethal agent in its execution protocol from a compounding pharmacy. The Department of Corrections would have a compounding pharmacist perform a non-traditional form of compounding, by manufacturing what is essentially a copy of an FDA-approved pentobarbital drug product, not pursuant to the determination of a licensed physician ("a learned intermediary") that an FDA-approved product cannot be used for medical reasons, but instead for the use in executing prisoners. Because neither the pharmacist nor the prescribing physician is fulfilling the professional role as the prisoners' learned intermediary, this non-medically-directed compounding is tantamount to drug counterfeiting. The

resulting dosage form is experimental and unpredictable in both composition and with respect to intended and unintended adverse effects.

II. Ingredients Used In Compounding Pharmacy

16. The quality of raw bulk product, or Active Pharmaceutical Ingredients ("APIs"), used in compounding is suspect. A 2000 hearing before the House Energy and Commerce Committee cited compounding pharmacies as a primary route of entry for counterfeit bulk drugs: "Lured by high prices and potential profits in the United States, counterfeit bulks can get into our prescription drugs in several ways: (1) as imported ingredients to U.S. manufacturers; (2) as imported ingredients to pharmaceutical compounders; and (3) as source ingredients for Internet pharmacies marketing to the U.S. The counterfeiters use sophisticated methods such as preparing false labeling, containers, seals and certificates of analysis, or using a manufacturing process that differs from the filed manufacturing process." Former FDA Commissioner Jane Henney testified that "[counterfeit bulk drugs] pose a real or potential health hazard because their manufacturer is often unknown" and that the "impurity profile is unknown, and the age, the storage, the manufacturing environment, or the synthesis of the product cannot be determined" creating a situation where "no amount of finished product testing can build quality into the product."

17. Compounding pharmacists generally do not have the ability to test chemicals for identity, potency, purity and contamination. Because of Missouri's secrecy laws as invoked by the Department of Corrections, the pharmacy preparing the pentobarbital sodium injection and the source of the pentobarbital sodium API are unknown at this time. It is unlikely that the pharmacy supplying pentobarbital to the Department of Corrections is capable of conducting testing to confirm the identity of the chemical, or to identify the presence of harmful contaminants that pose an immediate safety threat if administered intravenously. It is similarly unlikely that the compounding pharmacy intends to have either (a) the inactive chemical ingredients, or (b) the finished and compounded dosage form of the drug, tested using methods of analysis that meet the standard of care the law demands under normal circumstances. Missouri's execution protocol does not include any such provisions.

18. The ability to trace the raw API chemicals used in compounding back to the original manufacturers for information on quality, packaging, storage, shipment conditions, and chains of custody that are necessary to ascertain the identity, purity, potency, and efficacy of a medication is incredibly difficult even without the layer of secrecy added by the Missouri Department of Corrections.

19. The active ingredients used in the compounding pharmacy may come from the grey market, having been produced in non-FDA-registered, non-FDA inspected facilities. Ambiguous or false marketing statements are frequently used to mislead physicians into authorizing prescriptions for non-FDA-approved medications. The prescribing physician may believe that if ingredients are FDA-approved, they must be safe to use in compounding. But such a belief would rest on a false assumption. In fact, the FDA inspects chemical plants but does not approve chemical ingredients: it approves products in their finished dosage forms, with packaging and labeling to support safe use. Chemicals used in compounding are highly suspect, and there is no practical way to verify their quality, constitution or uniformity in limited pharmacy settings.

20. The ingredients often come from plants in China or India, which may or may not be registered with or have records of inspection by the US FDA. In this case, there is no evidence that the pentobarbital sodium selected for use in the non-traditional compounding of what is essentially a copy of an FDA-approved drug has been produced in an FDA-registered and inspected facility. Plants in China have been identified in which pesticides are manufactured using the same equipment as is used to make APIs bound for human ingestion as part of a compounded-pharmacy product. By contrast, for an active ingredient to

qualify for use in a finished dosage form, it must be manufactured in a US FDA-approved plant by a manufacturer which holds a Drug Master File for the chemical. (In any event, the Missouri Department of Corrections has concealed the identity of the chemical manufacturer and subsequent distributors/repackagers.) If one were to assume that pharmacists were able to verify the registration status of repackagers from which they purchase chemicals, it remains practically impossible for pharmacists to independently verify the registration status of the actual chemical manufacturer, due to complexities and vulnerabilities in global supply chains.

21. Ethical chemical manufacturers who adhere to professional Responsible Care principles are unlikely to sell chemicals that may be used in grey market drug production operations (non-traditional pharmacy compounding or "manufacturing under the guise of pharmacy compounding"). Instead, they are more likely to sell directly to FDA-approved manufacturers of finished products. Accordingly, non-FDA registered chemical manufacturers are more likely to release large quantities of bulk chemicals into the grey market, increasing the likelihood that substandard chemicals will serve as the starting materials for both traditional and non-traditional compounding.

22. In this unregulated market, a chemical labeled to represent a certain active ingredient may actually contain another, quite different ingredient. Practitioners, regulators, and experts have identified this problem as to chemicals distributed in large quantities to pharmacies throughout the nation for use in compounding.

23. There can be no guarantees that APIs purchased from the grey market are safe for use, are not contaminated, or even contain the ingredient listed on the product label. Furthermore, because chemicals may not have been manufactured in an FDA-registered facility under current Good Manufacturing Practice standards (GMP) standards, there can be no assurance as to the quality variation from lot to lot or container to container.

24. Testing for one lot of a chemical does not prove that a subsequent lot would have the same characteristics as the lot that was tested, and testing would provide only very provisional indication of its suitability for compounding given the unknown disposition of the chemical in the timeframe from testing to pharmacy compounding and use.

25. In order to represent to the Court or otherwise that a substance will have the effect it is supposed to have, one must use ingredients manufactured by FDA-registered and inspected manufacturers in order to ensure the quality of the

final product. If poor quality ingredients are used, even the best compounding practices will not build quality and suitability into the final product. The compounded drug may be contaminated, super-potent or sub-potent, making it dangerous in that it poses a foreseeable risk of pain and suffering to the "patient" to whom it was administered.

26. Even for the treatment of animals, the American Veterinary Medical Association actively discourages the use of compounded drugs except in cases of veterinary medical necessity. This professional policy was recently underscored after the death of 21 polo ponies from poisoning by compounded drugs. The American Veterinary Medical Association advises that because one cannot assure the quality of bulk active ingredients, bulk active ingredients must not be compounded for use in animals. The risk of contamination is extremely high, and veterinary associations draw an ethical line to avoid the risks of administering contaminated drugs to animals.

27. The Missouri Department of Corrections has not disclosed any evidence that the API in this case was manufactured in an FDA-registered facility. There is also no evidence that the API meets U.S. Pharmacopeia standards required for the finished dosage form: there is no way of knowing the current quality of the API in the bottle, after manufacture and initial testing (if

performed), and after supply-chain, repackaging and pharmacy handling. The Department has not disclosed preliminary evidence and additional verification of production in a facility that is registered and inspected by FDA in any compounding process. Administering such an ingredient introduces an unacceptable risk of harm and is ill-advised.

28. Pentobarbital injection compounded from unverified ingredients poses a substantial risk of harm from the ingredients alone: the use of untested, inadequately tested and/or non-validated formulas and compounding methods, environmental controls and container packaging, coupled with lack of instructions for safe use introduces very high burdens of uncertainty and risk of harm. These risks of harm include sub- or super- potency, contamination with dangerous allergens or substances that may cause immediate anaphylactic reactions, contamination with bacteria or fungus with immediate excruciating effects before the condemned person is unconscious (assuming it works even to that extent), and even the administration of an entirely incorrect chemical or active ingredient.

29. In the wake of the fungal meningitis outbreak of fall 2012 due to contaminated injectable steroids manufactured by a Massachusetts compounding pharmacy, the FDA has increased its scrutiny of compounding pharmacies and

found widespread safety risks for 30 out of 31 pharmacies inspected. FDA Commissioner Margaret Hamburg, in a related "Sixty Minutes" interview in April 2013 stated: "...what I think emerged in the meningitis outbreak was that many patients and their health care providers didn't realize that they in fact were using a compounded product." The interviewer then asked "As Commissioner of the FDA then you can't tell us sitting here now that every drug being used in the United States is safe and effective?" Hamburg replied, "No. I really cannot". If the Commissioner of the U.S. FDA cannot verify that drugs produced in compounding pharmacies are safe and effective for therapeutic use, doctor(s) and compounding pharmacist(s) involved in the prescribing and manufacture of drugs used for non-therapeutic procedures such as lethal injections should have even less confidence in their purity and potency, and subsequently their intended and unintended effects.

30. To use drugs from compounding pharmacies in the execution by lethal injection of a prisoner presents a substantial risk that the drugs will not work effectively for the announced purpose. Compounded pentobarbital may give rise to a completely unanticipated response including an allergic or anaphylactic reaction to an unidentified adulterant arising from intrinsic contamination of the ingredients or extrinsic contamination during the compounding procedure, or a

pulmonary embolism arising from unanticipated drug incompatibilities, or partial or complete lack of effect due to ingredient tampering or controlled drug diversion after analytical testing—circumstances that would be expected to prolong the execution and multiply the pain and suffering beyond the objective of causing the condemned person's death. Highly unpredictable, rapidly evolving, and potentially painful and agonizing reactions may ensue should the pentobarbital be contaminated by endotoxins or exotoxins. Similarly, should solid particulate matter of any kind contaminate the solution or precipitate out of solution during intravenous injection, there is a substantial risk of pain and suffering upon injection of the solution.

31. With a compounding-pharmacy product used instead of an FDA-compliant product, there is a substantial likelihood that the pH (acidity) of the solution injected will be incorrect. When the pH of the solution is incorrect, Plaintiffs will experience a burning sensation on injection analogous to the effect of injecting an unanethetized condemned person with potassium chloride.

32. The use of non-sterile and potentially contaminated active ingredients creates a serious risk of harm, including primary risks of infection and toxic blood reactions from bacterial, fungal and endotoxin contamination. It is foreseeable that the presence of adulterants or growing organisms will accelerate

chemical degradation, and that larger than expected moisture content will result in inaccurate weighing. If they occur, such initial compounding conditions will logically result in products that are sub-potent and will fail to attain the results expected of the substances with which health-care providers, regulators, and academics have practical experience and theoretical knowledge.

33. As noted, failure of the dosage form to attain or maintain the necessary pH will increase the likelihood of a burning sensation on injection. An analogous effect to be anticipated is the formation of precipitates, or solid particles of drug and other substances, with the foreseeable result of a painful pulmonary embolism in the most serious of cases. Bacteria and fungus are living organisms that grow and reproduce—their present and metabolic capacity in a solution may alter important quality attributes of the solution, including final pH, with the potential to create instability and/or incompatibility with human blood. In this case, compounding a copy of a non-human formulation—untested in humans and with a higher concentration compared with the FDA-approved human formulation—presents a substantial risk that the injection of the Department of Corrections' compounded drug will, for a variety of reasons, cause unnecessary and lingering pain and suffering.

34. There is also a substantial risk that the Department will administer a sub-potent dose of pentobarbital, resulting in less than effective depression of the central nervous system. The pentobarbital solution will be made of a proportion of water and active ingredient. There does not appear to be any mechanism within Missouri's execution protocol to adjust measurements to account for the hygroscopic (water absorbing) nature of the chemical. In all circumstances, non-adjustment for the hygroscopic nature of a chemical will result in a concentration lower than the intended concentration. The difference will depend on the actual water content of the API. If unaccounted for, this known reduction in potency owing to water content adds to other known threats regarding the purity and potency of the drug as it exists at the time of compounding, its potential for degradation after initial testing, its potential for intentional or unintentional adulteration, its potential for mislabeling, all of which, added together, increase the risk of formulating a sub-potent dosage form. If pentobarbital is administered in a non-lethal dose, the prisoners will foreseeably experience symptoms of acute but not lethal intoxication including nausea and vomiting, symptoms of life-threatening but not fatal respiratory depression and corollary organ damage (including brain damage), and paradoxical central nervous system excitation.

35. There is also a substantial risk that compounding error could result in a super- or sub- potent injection. Foreseeable consequences of the administration of a super-potent drug include suffocation and gasping for breath, before the loss of consciousness.

III. The Compounding Process

36. Drug manufacture is highly technical, requiring strict adherence to current Good Manufacturing Practice (GMP) and a rigorous and continuous process of FDA inspection, regulation, supervision and oversight.

37. The manufacture of sterile drugs intended for intravenous administration, such as pentobarbital, is acknowledged by pharmaceutical manufacturers and the FDA alike to be one of the most difficult of all pharmaceutical processes to execute. The preparation of sterile drugs is unavoidably complex, often involving many steps and manipulations. Each step poses an opportunity for error, including unintended introduction of adulterants, bacteria or fungus.

38. Unlike manufacturers, compounding pharmacies do not have to adhere to the rigorous FDA-approved procedures for manufacturing sterile drugs. Instead, the less rigorous United States Pharmacopoeia (USP) 797 chapter standards are applied to compounders. As a result, the potential for product

contamination in compounded drugs is far higher than that in manufactured drugs. In some states, compliance with even this lesser standard is not required by Boards of Pharmacy.

IV. Testing

39. Several studies, including a survey conducted by FDA in 2001, have reported a high prevalence of quality problems with various pharmacy-compounded drugs, including sub-potency, super-potency, and contamination. A survey of compounded drug products was conducted by the FDA in 2006 to explore these issues further. The results showed that thirty-three percent of the compounded drugs failed analytical testing using rigorously defensible testing methodology.

40. Further testing by the Missouri Board of Pharmacy, which is the only state agency which regularly tests compounded drugs, revealed that compounded drugs fail tests for potency and purity on average around twenty-five per cent of the time, an unacceptable failure rate consistent with rates observed by FDA. This is an extremely high failure rate, further supported by recent FDA inspection observations related to absent or limited sampling and testing of compounded drug products that would serve to identify substandard products prior to distribution.

V. Compounded Pentobarbital In Executions

41. Compounded drugs have been shown to be unreliable in purity, potency, safety and effectiveness, and have contributed to significant morbidity and mortality threatening public health and safety throughout the United States. This should be expected due to the abject lack of regulation and oversight of the compounding pharmacy sub-industry. The FDA states categorically that, because of their very nature, the safety and effectiveness of compounded drugs cannot be established. Drugs that are manufactured in developed and even developing countries with federal oversight of drug manufacturing are likely to be of a better quality and uniformity than compounded drugs produced without federal oversight in the United States. Here, we have none of the assurances afforded by US FDA or EU oversight, and in this case, the manufacturer of the API (and middlemen) are undisclosed due to the Missouri Department of Corrections' secrecy concerning the compounding pharmacy from which it intends to purchase pentobarbital.

42. Compounded drugs exist outside of the FDA regulatory framework and their quality, safety and effectiveness cannot be assured. In fact, they have a much higher probability of being substandard (sub- or super- potent, contaminated or of poor quality). In the context of executions by lethal injection,

introducing a further element of unpredictability by using compounded drugs is a wanton invitation to pain and suffering over and above the statutory objective of the death of the condemned person.

43. Physician experts in the branches of pharmacology known as pharmacokinetics and pharmacodynamics are qualified to render opinions on the effect of drugs including pentobarbital sodium in living organisms including humans in research and clinical settings. Pharmacokinetics involves the study of the absorption, distribution, metabolism, and excretion of drugs in animals and humans. Pharmacodynamics is the study of the pharmacological effects of a drug on the body. This type of study involves FDA approved drugs or the use of highly purified research chemicals in laboratory animals.

44. What is in question here, with Missouri's proposed execution method, is the quality and safety of pharmacy compounded pentobarbital sodium injection produced from a bulk drug substance or active pharmaceutical ingredient from an unknown source and of unknown composition prepared under unregulated conditions not meeting FDA Good Manufacturing Practice (GMPs) guidelines, rather than the pharmacological effect of FDA approved pentobarbital sodium in human subjects.

45. I have reviewed the report of Dr. Mark Dershwitz, dated October 20, 2013. He opines that pentobarbital "will result in the rapid and painless death of the inmate to whom it is administered." That opinion does not address the compounded pentobarbital at issue here, for which the final composition is unknown, as opposed to the use of FDA-approved pentobarbital and the assurances of safety, effectiveness, and purity that accompany it.

46. Starting with poor quality and/or contaminated pentobarbital sodium API combined with potential errors in compounding and lack of adherence to GMP guideline and sterility standards, is likely to result in substandard, contaminated or super- or sub-potent pentobarbital. There is a substantial risk that if such drugs were used in an execution by lethal injection, they would not work in a predictable manner, and could cause serious pain upon injection, considerable mental anguish and anxiety, and thereby put the prisoners at substantial risk of serious, unnecessary and substantial harm and mental anguish.

Further, affiant saith naught.

Dated this 7th day of November, 2013.

Larry D. Sasich

Sworn to and subscribed before me
this 7th day of November, 2013.

NOTARY PUBLIC

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EDUCATION

1995 to 1997	Master of Public Health - Epidemiology The George Washington University School of Public Health and Health Services Washington, D.C.
1974 to 1975	Doctor of Pharmacy University of the Pacific College of Pharmacy Stockton, California
1966 to 1970	Bachelor of Science Pharmacy Idaho State University College of Pharmacy Pocatello, Idaho

RESIDENCY

1986 to 1987	Nuclear Pharmacy University of New Mexico College of Pharmacy Albuquerque, New Mexico

PROFESSIONAL LICENSES

1970 to Present	California RPH 27094

PROFESSIONAL EXPERIENCE

April 2013 to date	Consultant, Drug Policy, Drug Safety and Efficacy North Bay, ON Canada
July 2007 to April 2013	Consultant, Saudi Food and Drug Authority 3292 Northern Ring Rd. Al Nafal District Riyadh, Saudi Arabia
November 2009 to 2012	Consultant, Public Citizen's Health Research Group 1600 20th Street, NW Washington, D.C. 20009
2007 to 2009	Chairman, Department of Pharmacy Practice LECOM School of Pharmacy 1858 Grandview Blvd. Erie, PA 16505
2006 to 2007	Acting Chairman, Department of Pharmacy Practice LECOM School of Pharmacy 1858 Grandview Blvd. Erie, PA 16505
2005 to 2006	Assistant Professor, Department of Pharmacy Practice LECOM School of Pharmacy 1858 Grandview Blvd. Erie, PA 16505
2006 to 2008	Consultant Centre for Science and the Public Interest – Canada Suite 4550, CTTC Bldg. 1125 Colonel By Drive Ottawa, Ontario K1S 5R1 Canada

PROFESSIONAL EXPERIENCE

2005 to 2007	Consultant Public Citizen's Health Research Group 1600 20th Street, NW Washington, D.C. 20009
2005 to 2006	Consultant Canadian Agency for Drugs and Technologies in Health 600-865 Carling Avenue Ottawa, Ontario K1S 5S8 Canada
1995 to 2005	Research Analyst Public Citizen's Health Research Group 1600 20th Street NW Washington, D.C. 20009
1991 to 1995	Drug Information Pharmacist King Faisal Specialist Hospital and Research Centre Riyadh 11211, Saudi Arabia
1993 to 1996	Adjunct Clinical Faculty Welch School of Pharmacy University of Wales Cardiff, Wales
1992 to 1995	Clinical Instructor College of Pharmacy King Saud University Riyadh, Saudi Arabia Graduate and Undergraduate Teaching
1988 to 1990	Clinical Pharmacist St. Helens Hospital and Health Center St. Helens, OR Emanuel Hospital and Health Center Portland, OR
1985 to 1988	Associate Professor of Clinical Pharmacy Idaho State University College of Pharmacy Pocatello, Idaho Promoted and Tenured July 1, 1984

PROFESSIONAL EXPERIENCE

1983 to 1984	Assistant Professor of Clinical Pharmacy College of Pharmacy Idaho State University Pocatello, Idaho
	Acting Associate Dean for Student Affairs
1982 to 1983	Assistant Professor of Clinical Pharmacy College of Pharmacy Idaho State University Pocatello, Idaho
	Director of Professional Practice
1979 to 1982	Assistant Professor of Clinical Pharmacy College of Pharmacy Idaho State University Pocatello, Idaho
	Director, Idaho Drug Information Service and Regional Poison Control Center
1976 to 1979	Assistant Director of Pharmacy Services USA MEDDAC Berlin, West Germany
1975 to 1976	Staff Pharmacist USA MEDDAC Wuerzburg, West Germany
1970 to 1974	Pharmacist Baneth's Pharmacy Menlo Park, CA

HONORARY SOCIETIES

1982	Rho Chi
1982	Sigma Xi

AWARDS

2000	Distinguished Person of the Year – Pharmacists Planning Services
1995	Fellow American Society of Health-System Pharmacists
1986	Ciba-Geigy Leadership Award
1983	Outstanding Service – Idaho Board of Pharmacy
1982	Phi Delta Chi Faculty Achievement Award

APPOINTMENTS

2009	FDA Science Board Sub Committee on the Center for Food Safety and Applied Nutrition (CFSAN)
2008	FDA Science Board Sub Committee on the review of the National Center for Toxicological Research
2007	Grant Reviewer U.K. Economic and Social Research Council Large Grant proposal: Governance of Pharmaceuticals and Health
2007	Consumer representative, Science Board to the Food and Drug Administration – advisory committee to the FDA Commissioner
2007	Pennsylvania Pharmacists Association Pharmacy Compounding Task Force
2006	Food and Drug Administration Pediatric Advisory Committee November 16, 2006 – substitute consumer representative
2006	Reviewer *PLoS Medicine*
2000	Reviewer for the *Western Journal of Medicine*
2000	Reviewer for the *Journal of the American Medical Association*
1996	Department of Health and Human Services Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Drug Information
1996	Department of Health and Human Services, Food and Drug Administration, Consumer Consortium

APPOINTMENTS

1995	Reviewer for the *Saudi Pharmaceutical Journal*
1993	Reviewer for the *Annals of Saudi Medicine*
1986	Reviewer for *Annals of Pharmacotherapy*
1987	Idaho Delegate to Western Regional Conference on Clinical Pharmacy Practice
1985	Idaho Health Systems Ethics Conference Task Force
1984	American Pharmaceutical Association Committee to prepare accreditation standards for a community pharmacy residency
1982	Assistant Editor DRUGDEX®
1981	USP Dispensing Information Contributors Panel

PUBLICATIONS

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